



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/32		A1	(11) International Publication Number: WO 98/14125 (43) International Publication Date: 9 April 1998 (09.04.98)
<p>(21) International Application Number: PCT/US97/17426</p> <p>(22) International Filing Date: 26 September 1997 (26.09.97)</p> <p>(30) Priority Data: 08/720,699 2 October 1996 (02.10.96) US</p> <p>(71) Applicant: SPECIALIZED HEALTH PRODUCTS, INC. [US/US]; 655 East Medical Drive, Bountiful, UT 84010 (US).</p> <p>(72) Inventors: THORNE, Gale, H.; 1056 Millcrest Circle, Bountiful, UT 84010 (US). THORNE, Gale, H., Jr.; 1898 South Chokecherry Drive, Bountiful, UT 84010 (US). OWEN, Charles, V.; 10754 North 6000 West, Highland, UT 84003 (US). STOUT, Gary, H.; 1333 North 1700 West, Farmington, UT 84025 (US). FARNE, Tim, L.; 287 North Springridge Drive, North Salt Lake, UT 84054 (US).</p> <p>(74) Agents: EVANS, Paul, S.; 1661 Somerset Court, Farmington, UT 84025 (US) et al.</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	
<p>(54) Title: LANCET APPARATUS AND METHODS</p> <p>(57) Abstract</p> <p>A one-time-use, self-powered, disposable lancet apparatus (700, 750, 800, 900) packaged both as strips (600) comprising a plurality of lancets (41') and as individually packaged lancets (700, 750, 800, 900). A novel lancet blade design comprises means (515) for attaching each blade (500, 500') in a loader stack for an automated assembly machine. Individually packaged lancets (700, 750, 800, 900) are disclosed in both one-step (750, 800, 900) and two-step (700) embodiments. In each case, every lancet (700, 750, 800, 900) comprises a self-contained package (802) which houses a powered lancet blade (500, 500') before use and a spent blade (500, 500') after use to assure safety from inadvertent sticks both before and after a lancing procedure.</p>			

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LANCET APPARATUS AND METHODS**FIELD OF THE INVENTION**

5 This invention relates generally to lancets and more particularly to novel, self-contained, precocked and single-use lancets which, when activated, extend a tip of a lancet blade outward from a lancet housing and back into the housing for safe disposal. In a preferred embodiment, the housing is sealed to maintain sterility of the blade before use. A portion of the housing is preferably frangible, and the portion is
10 franged to initiate a single lancing cycle and to subsequently make the lancet unreusable.

BACKGROUND OF THE INVENTION

In particular, U.S. Patent Number 5,514,152 (Smith), issued May 7, 1996,
15 discloses a lancet having a cocked torsion spring wound about a centrally disposed hub frangibly connected to a lancet housing. Generally, the housing is disclosed to be a container for a plurality of lancets, each of which, after use, is frangibly separated from the rest of the strip and individually discarded. The spring is directly interconnected to a lancet blade in a cam/cam follower relationship. When the hub is
20 frangibly separated from the housing, the cocked spring is released to drive a lancet blade tip linearly from the housing and then return it safely back into the housing.

Smith discloses frangible separation of the hub from the housing where a base of the hub is annularly connected by sharp corners to the housing. It is taught that stress placed upon the base causes the hub to frange from the housing, permitting the
25 lancing cycle to begin. Of course, before each lancing cycle is initiated, a housing

exit is exposed to provide an orifice through which the lancet blade tip travels. It is only when the orifice is provided that the sterility of the package is compromised, thereby making the blade and internal contents sterile until that time.

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SUMMARY OF THE INVENTION

In brief summary, this novel invention alleviates all known major problems related to providing a molded housing for both a lancet strip and single lancet device and further combines a lancet carrier with a lancet housing into a unitary single lancet device. One and two activation step embodiments of the single lancet devices are disclosed, the one step embodiments being presently preferred. Generally, the one step embodiments comprise a single action (step) by a user; however, two functions (breaking of a sterile barrier and initiation of a lancet cycle) are combined in the single step. Commonly, the two step embodiments require a first step to break a sterile barrier and a second step to initiate a lancet cycle. While there are few other advantages or disadvantages to one or two step operation, the first step of the two step embodiment is often regarded as causing lost or wasted time by a user.

Similar to Smith (cited above), the invention comprises a rapid outwardly driven and then inwardly retracted lancet blade in a cycle, which is initiated by franging a hub, disposed within and securely affixed to a cocked spring, from an integrally associated housing. This invention, however, embodies a novel molded interconnection between the hub and housing to assure that the hub will be easily franged from the housing and will rotate freely within the spring. Moreover, the molded interconnection does not comprise extraneous fragments about the edges at

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frange sites, which can catch upon other edges of the housing and inadvertently keep the spring from unwinding and preventing the blade from completing a lancing cycle.

Accordingly, it is a primary object of the present invention to provide a one-time-use, self-driven lancet having a readily frangible, molded connection between a hub and housing which permits the hub to separate from the housing without extraneous fragments being disposed about the hub where the hub/housing frange is disposed.

It is another primary object of the present invention to provide a single, one-time-use lancet embodiment in which a carrier and lancet housing are combined in a single disposable unit.

It is an important object of the present invention to provide an embodiment of the single, one-time-use lancet which operates in two steps, one of which is to break a sterile barrier and the other of which is to initiate a lancet cycle.

It is a further object of the present invention to provide an embodiment of the single, one time use lancet which operates in a single step, wherein the breaking of a sterile barrier and initiating of a lancet cycle are performed in a single operating step.

It is another object of the present invention to provide an embodiment of the single, one-time-use lancet which operates in the single step of squeezing two displaced, but juxtaposed parts together to perform the two steps of breaking the sterile barrier and initiating the lancet cycle.

It is yet another object of the present invention to provide a lancet blade which is facilely used in automated assembly of a lancet.

It is an additional object of the present invention to provide a strip of presterilized lancets from which a used lancet is frangibly separated without disturbing the sterile condition of any other lancet in the strip.

It is a further object of the present invention to provide a lancet housing having a molded hub which is freely, frangibly separated from the rest of the housing.

These and other objects and features of the present invention will be apparent from the detailed description taken with reference to accompanying drawings which follow, or may be learned by the practice of the invention.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a planar view showing the inner surface of a related art representation of a lancet housing assembly member.

Figure 2 is an exploded perspective view of a related art lancet housing assembly compartment of the lancet housing assembly member shown in Figure 1, comprising a lancet blade and torsion spring in cocked orientation.

Figure 3 is a planar view of the inner surface of a related art representation of a cover for the lancet housing assembly member shown in Figure 1.

Figure 4 is a planar view of the inner surface of the lancet housing assembly member seen in Figure 1 with the torsion spring and lancet blade in place and adhesive distributed on the higher surfaces.

Figure 5 is a top elevation of an assembled lancet housing assembly compartment seen in Figure 1 without a cover.

Figure 6 is a top elevation of a lancet compartment depicted in Figure 5, showing a fired lancet in mid-cycle wherein a tip of a lancet blade, which is a key part of a lancet assembly, is protruding from the lancet compartment.

Figure 7 is similar to Figure 5, but showing a spent lancet with the lancet tip retracted into the lancet compartment.

Figure 8 is a section taken along lines 8-8 in Figure 4; shown without a lancet for clarity of presentation.

Figure 9 is a perspective drawing showing a related art representation of the direction of insertion of a lancet housing into a housing carrier.

Figure 10 is a perspective drawing showing the initial position of the lancet housing shown in Figure 9 and properly inserted into the housing carrier.

Figure 11 is a perspective drawing of the housing and carrier illustrated in Figure 10, showing the distal end of a lancet compartment newly exposed by frangible separation from a preceding compartment and revealing an exit aperture for a first to-be-used lancet.

Figure 12 is a perspective drawing of the housing and carrier illustrated in Figure 11, showing a used lancet compartment frangibly separated from the remainder of the housing and revealing an exit aperture for a next to-be-used lancet.

Figure 13 is a top elevation view of a lancet blade of the present invention.

Figure 14 is a perspective of a plurality of blades affixed to a blade magazine for automatically loading blades into the lancet housings.

Figure 15 is a perspective of a strip of lancets comprising a blank section disposed between each lancet.

Figure 16 is a perspective of the strip of lancets shown in Figure 16 with a blank section frangibly separated from the rest of the strip to expose a shroud about an exit and reentry slot for a lancet blade.

Figure 17 is an inverted section along lines 17-17 of Figure 15.

5 Figure 18 is a segment of a section along lines 18-18 of Figure 15.

Figure 19 is a perspective of an unused single lancet comprising a lancet actuating arm prominently disposed on the outside of an outer lancet housing.

Figure 20 is a perspective of the lancet shown in Figure 19 after a completed lancing cycle.

10 Figure 21 is a perspective of another unused single lancet housed in a self-contained transport package.

Figure 22 is a perspective of the single lancet of Figure 22, after the lancet has been used.

15 Figure 23 is a cross section along lines 23-23 of Figure 21, with some parts removed for clarity of presentation.

Figure 24 is a perspective of an unused lancet disposed for protection in a bubble pack to retain lancet sterility.

Figure 25 is a perspective of the unused lancet shown in Figure 19 and removed from the bubble pack for use.

20 Figure 26 is a perspective of the lancet of Figure 25 after use.

Figure 27 is a top elevation of another single unused lancet with parts removed for clarity of presentation.

Figure 28 is a top elevation of the lancet shown in Figure 27 after use.

DETAILED DESCRIPTION OF THE INVENTION

In this description, the term proximal is used to indicate the segment of a device or other apparatus normally closer to a user when the device is properly used. The term distal refers to a direction which is farther removed from the user than a segment which is proximal. Reference is now made to the embodiments illustrated in Figures 1-28 wherein like numerals are used to designate like parts throughout. In order to properly reference novelty of the instant invention, a summary of a portion of the disclosure found in Smith is provided and referenced as related art.

Reference is made to Figure 1 which shows the inner surface of a lancet assembly member 10 of the preferred embodiment of Smith. Assembly member 10 comprises distal end 20, proximal end 30, and multiple empty housing compartments 40 separated by frangible segments 42 whereat the housing compartments can be easily and manually separated without special tools. Assembly alignment pin holes 44 and 46 are also shown. Construction of each housing compartment 40, which is an integral operating portion of each individual lancet 41, is substantially the same as each of the others. As can be more easily seen in Figure 2, typically each housing compartment 40 comprises a hub 50, a torsion spring anchor slot 62 which is an integral part of hub 50, a lancet blade slide plane 70, guides 80 and 81, and at least one frangible section 90, associated with frangible segment 42. Hub 50, placed substantially in the center of compartment 40, is part of the lancet triggering mechanism disclosed in detail hereafter. Groove 60 across the centerline of hub 50 provides a locking apparatus for that part of a torsion spring which will drive the lancet when the spring is freed to unwind. The torsion spring anchor slot 62 holds a

lower end of the torsion spring immobile in compartment 40. Lancet slide plane 70 is inset below an inner surface 92 to provide parallel lancet edge guides 80 and 81 which provide a controlled line of travel on each side of a lancet blade. The lancet slide plane 70, edge guides 80 and 81, and a travel limit edge 94 (described in detail hereafter), each being an integral part of the lancet structure and function, are included in the encapsulating housing structure in this embodiment.

A channel 96 which is an extension of slide plane 70 extends across a frangible area 42 such that, when a top cover completes the housing and separation occurs at frangible section 90, an egress/ingress port or aperture 98 is opened. The line of separation is determined by a "V" groove having an apex at section 90 and formed by compartment end apparatus comprising vertical end 102 and slanted end 104. The function of the frangible section and end apparatus is discussed in more detail hereafter.

Other than a spring release associated with hub 50, the moving parts of a total lancet assembly 100 (best seen in Figure 2) comprise torsion spring 110 and lancet blade 120. A preferred embodiment of torsion spring 110 in Smith is shown in Figure 2. Spring 110 comprises spring wire wound into a torsion spring having a lower end 122 which extends horizontally outward from a central core 123 of spring 110. On the other end, spring 110 is bent centrally such that it forms a straight horizontal segment 124 which can be locked into groove 60 when the wound torsion spring 110 is press-fit over hub 50. To assemble a lancet according to Smith, a tightly wound torsion spring 110 is pressed over hub 50 such that the lower spring end 122 is firmly affixed into anchor slot 62 and the horizontal straight spring section 124 is firmly

pressed into groove 60. At the wire end of straight segment 124 the spring is bent vertically upward forming crank arm 126, which is used to form an interlock between torsion spring 110 and a coupling slot 130 of lancet blade 120. Thus, crank arm 126 comprises a cam and arcuate coupling slot 130 comprises a cam follower. The 5 cam/cam follower structure, sometimes referred to as a track structure, provides rotary to linear motion translation.

In Smith, lancet assembly 100 comprises lancet blade 120 which is of unitary, stainless steel construction comprising a very sharp lancet tip 140, torsion spring 110, coupling slot 130, guide edges 132 and 133, and leading edge 134. To complete 10 assembly of lancet bottom housing 10 in a compartment 40, lancet blade slot 130 is placed over the already positioned torsion spring crank arm 126 such that lancet blade 120 lies on slide plane 70 with lancet tip 140 in channel 96 and edges 132 and 133 in line with edge guides 80 and 81.

A top elevation view of lancet bottom housing 10, having a plurality of lancet 15 blades 120 and springs 110 assembled therein, is shown in Figure 4. A housing cover, which normally covers the lancet bottom housing 10, is not shown for clarity of presentation but is described in detail hereafter. Torsion spring 110 is cocked and held firmly in place by a slot 62 and a groove 60. Before lancet blade 120 can be fired, the lancet tip 140 exit aperture 98 is opened by frangibly separating the lancet 20 bottom housing 10 within a frangible area 42.

The lancet is actuated by breaking the attachment of the hub 50 free from the compartment 40. One mode of actuation is best seen in Figure 8, which is a section along lines 8-8 of Figure 4, with lancet blade 120 removed for clarity of presentation.

Hub 50 is connected to compartment 40 by a frangible diaphragm 142 comprising rounding annular corners 144 and sharp corners 146. Frangible diaphragm 142 comprises an annular actuator area 147 which first holds hub 50 from movement and, upon frangible actuation, releases hub 50 to rotate as forced by the released biasing memory of torsion spring 110. A recess 148 in diaphragm 142 causes actuator diaphragm 142 to be attached to hub 50 with a reduced cross section at sharp corners 146 forming actuator area 147. To actuate the lancet, an external force is applied to the recessed portion 148 of diaphragm 142, causing actuator diaphragm 142 and hub 50 to be deflected slightly. Note that the recess 148 makes inadvertent deflection more unlikely. A deflection causes stresses to be generated at sharp corners 146 and results in the fracture of hub 50 from actuator diaphragm 142 in the region of sharp corners 146. When viewed from inner surface 92, (see Figure 2) the freed hub 50 is released to spin in a counter clockwise direction as the biasing memory of the cocked torsion spring 110 is freed to unwind.

As can best be seen in sequence in Figures 5, 6, and 7, crank arm 126 moves in an approximately circular motion as hub 50 and spring 110 rotate, and crank arm 126 slides laterally in slot 130 as it drives the lancet tip 140 linearly outward through the egress/ingress port 98 from the face of frangibly separated section 90. As shown in Figure 6, lancet blade 120, guided by edges 80 and 81 and forced by crank arm 126, moves lancet tip 140 outward until crank arm 126 begins drawing blade 120 proximally back into cavity 40, which retards the leading edge 134 of the lancet blade 120 from colliding with travel limit edge 94. Leading edge 94 provides a safety limit for lancet blade tip 140 travel. In this manner, the depth of lancet tip 140 penetration

is precisely determined. The depth of puncture in the currently preferred embodiment is 1.7 to 3.0 millimeters.

Further unwinding of torsion spring 110 continues to drive crank arm 126 in a nearly circular counter clockwise direction causing lancet blade 120 to be retracted as shown in Figure 7, thereby completing translation of torsion spring 110 rotary motion to bi-directional linear travel of lancet blade 120. With a cover in place, lancet compartment 40, now containing a totally retracted spent lancet 120, is a safe disposable. There is no "bounce" or multiple excursion of lancet tip 140 from the housing because the forcing direction of the biasing memory of the torsion spring forces lancet blade 120 away from travel limit edge 94 and egress/ingress port 98.

An enveloping or encapsulating housing cover 150 is shown in Figure 3.

Cover 150 is inverted, disposed to cover a bottom 10 after assembly, and permanently affixed thereto by either adhesion, ultrasonic bonding or another plastic adhesion method, such as thermal bonding. Once a spring 110 and a blade 120 are mounted into each lancet compartment 40, cover part 150 is accurately positioned relative to bottom 10 through the use of alignment pins and holes or by ridges and grooves used in ultrasonic bonding to cover every compartment 40. It is important that the strip formed by joining bottom 10 and cover 150 form a hermetically sealed unit which does not require further packaging for transport prior to use.

Smith discloses that both bottom 10 and cover 150 members may be molded from synthetic resinous material such as, but not limited to, polymethylmethacrylate, filled polypropylene, polystyrene, and acrylics. Depending upon the material used,

bonding may be accomplished by using methods comprising adhesives, and thermal and ultrasound heating processes.

Either prior to or after encapsulation, all internal parts of the packets comprising a fully assembled lancet housing 200 (see Figure 9) with precocked lancets can be sterilized by radiation or like methods which are well known in the art, thereby making internally disposed finger piercing elements aseptic. Each lancet compartment is separately and hermetically sealed from all others such that contamination of the parts of one compartment does not contaminate parts of any other. Each encapsulated compartment 40 is its own hermetically sealed container and retains an aseptic condition until egress/ingress port 98 is opened.

Reference is now made to Figures 9-12 wherein a lancet strip 200 and carrier 400 are seen. In use, carrier 400 holds lancet strip 200 which comprises a joined bottom 10 and cover 150, for easier handling as strip 200 is serially shortened when each spent lancet housed in a compartment 40 is frangibly separated and discarded (see Figures 10-12). Carrier 400 also provides a special tool for triggering each lancet. Except for blank sections on proximal and distal ends 152 and 154, respectively, each individual lancet 41 is juxtaposed with and joined to an adjacent individual lancet 41, such that separating and discarding a lancet in a previously used individual lancet 41 generally results in exposing a lance blade exit orifice associated with a channel 96. If the newly exposed orifice is not used immediately, there is a significant likelihood that a portion of the lancet travel channel 96 will become contaminated before ultimate use. As Smith teaches a slot which forms channel 96, there is a greater likelihood that blood emitted from a lance site may contaminate an

area surrounding the carrier 400 or carrier 400 itself. It is one of the main objects of this instant invention to prevent that event.

In the following detailed description of the instant invention, items which are similar in form and function to those of the related art described in Smith are commonly denoted by the same reference number primed. As an example, an individual lancet which is similar in form and function, but not entirely identical, to individual lancet 41 is denoted by 41' (see Figure 15).

Attention is drawn to Figure 13 wherein a lancet blade 500 of the instant invention is seen. Blade 500 comprises a slot 130', which is similar in form and function to slot 130, and a sharpened lancing tip 140'. However, blade 500 differs markedly from blade 120 by proximally disposed protrusions 502 and 504 on blade 500. As best seen in Figure 13, blade 500 comprises an edge 506, transversely disposed to the direction of the travel of lancet tip 140' and proximally disposed relative to slot 130'. On one side, edge 506 curves arcuately away from slot 130' at a rounded corner 508 to travel normal to the general direction of slot 130' and then curves inward and then outward to form a bulbus inwardly protruding section 510. Edge 506 then continues outward and forward (distal) to complete an outline of blade 500. On the other side, edge 506 curves similarly, but as a mirror image, arcuately away from slot 130' at a rounded corner 512 to also travel normal to the general direction of slot 130' and then curves inward and then outward to form a second bulbus inwardly protruding section 514. From this point, edge 506 continues to define the entire circumference of blade 500.

The useful function of bulbous sections 510 and 514 is best seen in Figure 14.

As shown in Figure 14, an I-beam section 515 having front and back plates 516 and 518 and separated by a pair of channels 520 and 522, which are proportioned to accept insertion of bulbous section 510 and 514, respectively, when vertically disposed provides nesting support for a plurality of blades 500. At the bottom of I-beam section 515, a feeder system which is of a form for feeding small, flat pieces is disposed to act as an automatic gravity feeder for an automatic assembly machine (not shown). Such feeders and automatic assembly machines are well known in the automated assembly equipment art. By trapping and nesting a plurality of blades in such an I-beam 515, blades are captured at a manufacturing site and transported and then individually fed for assembly into an individual lancet during an automatic assembly process. The presently preferred mode of manufacture of blades 500 is through a process of coining. A two step coining process produces a blade having virtually no rough edges and a sufficiently sharpened blade for lancing.

Attention is now directed to Figure 15, wherein a strip 600 of individual lancets 41' generally interposed between blank parts 602 and 604 is shown. Strip 600 is comprised of a bottom part 10' and a cover part 150'. Parts 10' and 150' are similar in form and function to parts 10 and 150, but have marked and novel differences as disclosed hereafter. Each individual lancet 41' is frangibly separated from associated blank parts 602 and 604. It is preferred that blank part 604 be physically recognizable and separable from the other parts of strip 600 for ease of determining the direction of entry into a carrier. (See, for example, Figure 9.) Frange segments are denoted by segments alternately numbered 606 and 608 in Figures 15 and 16. Generally,

franging at segment 606 separates a blank part 604 or 602 from an individual lancet 41' to expose a surface 610 of the individual lancet 41' for a lancing operation (as seen in Figure 16).

It is important to note that the exposed surface 610 resulting from separating a
5 blank part (in Figure 16 the blank part is blank part 604), further exposes a shroud 612 about a slot (not seen, but similar to the slot which forms channel 96, shown in Figures 5-7 and 11 and 12). Shroud 612 is formed by an arcuate raised section 614 in an inverted bottom 10' in combination with a planar raised section 616 in an attached cover 150'. Note that the slopes on exposed face 620, formed in combination by parts
10 of bottom 10' and cover 150', effectively extend shroud distally outward from the rest of strip 600 to aseptically isolate the skin contacting areas of shroud 612. In this manner, blood and other material emitted from a lance site is either contained or effectively isolated from the distal portions of a carrier or other portions of strip 600 to be used later. Note also that shroud 612 comprises a sterile interior face 622 when
15 separated from a blank part 604 or 602. Thus, each subsequent individual lancet 41' presents a sterile, confined interface to its associated lance site.

Reference is now made to Figure 17, wherein a bottom section 630 of an individual lancet 41' is seen. Section 630 comprises a hub 50', which is substantially the same as hub 50 earlier described, and which comprises a groove 60 (substantially the same in form and function to groove 60 earlier disclosed). Further, bottom section 630 comprises an actuator diaphragm 142', which, as is the case of actuator diaphragm 142, is frangibly broken under pressure normal to a surface 632, which is a portion of diaphragm 142'.

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However, there is a major and critical difference between the structures of diaphragm 142 and hub 50 and of diaphragm 142' and hub 50'. Careful and detailed analysis of the frange lines associated with the parts molded in a form as disclosed for diaphragm 142 and hub 50 revealed that franging hub 50 from diaphragm 142 would often result in the creation of large fragments jutting outward from hub 50 and catching and impeding rotation of the hub and spring. This would cause the lancet blade to misfire or to not completely exit and return to compartment 40. Continued analysis showed an apparent characteristic flow path in molded parts which caused a somewhat surprising direction of development of a flow path and, therefore, a frange line. That path resulted in an annular frange path which was directed outward from a pressure placed upon a surface, such as surface 632. For this reason, an optimum frangible connection between a hub and an actuator diaphragm was determined to be through two annular grooves disposed about the base of the hub.

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Relative dispositions of such grooves (annular grooves 634 and 636) are shown in Figure 17. Two frange lines 638 and 640 are shown as examples of the effective area of franging where hub 50' separates from diaphragm 142'. Of course, these are only examples, but it is important that grooves 634 and 636 be so positioned and of a depth that they intersect such an annular frange as hub 50' separates from diaphragm 142'. It is also important that grooves 634 and 636 be separated by sufficient material to permit physical stability until pressure is applied to surface 632. By experimentation, it has been shown that optimal pressure is in the range of 10 to 30 pounds, and the thinnest material disposed between grooves 634 and 636 should be in the range of 0.010 inches (0.025 centimeters). Currently, the preferred material for

bottom 630 and an associated cover is polystyrene, thirty percent filled with a mineral filler, such as wollastonite. In a currently preferred embodiment, bottom 630 is ultrasonically bonded to a cover. For this purpose, pointed protrusions 642 are molded into the upper segment of bottom 630. Otherwise, lancet cavity 40' is similar in form and function to cavity 40 previously described.

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Figure 18 shows a longitudinal section of a portion of bottom 630 comprising a first disposed blank 604 and a first-to-be-used individual lancet 41'. Dashed line 644 denotes a frange line between blank 604 and individual lancet 41'. Franging along line 644 opens shroud 612, thereby providing an exit and reentry portal for lancet blade 500, not seen in Figure 18 for clarity of presentation. In Figure 10, the disposition of annular groove 634 relative to annular groove 636 is also seen. A next frange line 646, along which individual lancet 41' is broken away from the rest of other unused lancets, is proximally disposed relative to dashed line 644.

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Reference is now made to Figures 19 and 20, wherein a single lancet 700 (as opposed to a strip of lancets), is shown. Lancet 700 comprises an outer housing 702 and an inner housing 704. Outer housing 702 is a permanent part of lancet 700 and comprises a shroud portal 706 and an actuator button and lever 708. Further, the outer housing comprises a box-like shape having a superior surface 710, an inferior surface 712, a portal side 714, a closed side 716 and a back side 718. Disposed for slidable insertion of inner housing 704 into outer housing 702, outer housing 702 comprises a fourth side 720 having an opening for slidable movement of inner housing 704.

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Inner housing 704 comprises a cavity (not shown) which is referenced hereafter as cavity 41' due to its closeness in form and function with cavity 41'

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previously disclosed. However, rather than a direct and integral connection with a shroud, inner housing 704 comprises a substantially flat exit and entry portal 722 through which a lancet blade tip 140' passes during a lancing cycle. Though not necessary, it is presently preferable that portal 722 have a slightly raised surface 724 by which inner housing 704 is frangibly affixed to a juxtaposed surface of outer housing 702 before use.

An unused lancet 700 is seen in Figure 19. To prepare lancet 700 for use, inner housing 704 is translated laterally in the direction of arrow 725, perhaps by squeezing between a thumb and forefinger, until blade exit and reentry portal 722 is centrally disposed within shroud portal 706. Such a position is easily achieved as side 718 of outer housing 702 acts as a stop, thereby limiting travel of housing 704. In the process of providing the force for laterally translating housing 704 relative to housing 702, any portion of housing 704 which is affixed to housing 702 is frangibly separated. Thus, prior to exerting the lateral translation force, the parts involved in frangibly affixing housing 702 to housing 704 are best used to serve as a sterile barrier about portal 722.

Once lancet 700 is prepared for use, shroud 706 is disposed about a site to be lanced and actuator button and lever 708 is depressed to frangibly separate a hub 50' from an actuator diaphragm 142', as disclosed earlier. Separation of hub 50' releases a spring 110 and thereby drives blade 500 and its associated blade tip 140' through a lancing cycle, while leaving blade tip 140' safely confined in cavity 40' at the end of the cycle. It is evident that the step of preparation followed by a spring and blade actuation step inherently makes lancet 700 a two-step device.

Reference is now made to Figures 21-28 wherein the parts and perspectives of one-step devices are seen. One step devices are defined as lancets which are prepared for actuation and actuated in a single user movement. In Figures 21 and 22, a lancet 750 in an unused state (Figure 21) and in a spent state (Figure 22) is seen. Note that lancet 750 is similar in form to lancet 700. Lancet 750 comprises an outer housing 752 and an inner housing 754. The major difference, apparent from exterior views of lancets 700 and 750, is the lack of an actuator button and lever 708 on lancet 750.

Actuation of lancet 700 is caused by an internally disposed franging system which fires lancet 750 as inner housing 754 is transposed into outer housing 752. The mode of actuation of lancet 750 is clearly seen in Figure 23. As seen in Figure 23, inner housing 754 comprises a cavity 40', a spring 110, a blade 500, an actuator diaphragm 142" and a hub 50". The diaphragm 142" and hub 50" combination seen in Figure 23 primarily differs from the diaphragm and hub combinations disclosed previously by an outwardly protruding conical hump 756 having a common axis with hub 50". Note that, in line with hump 756, the outer housing 752 comprises an open channel 758. Channel 758 is closed by an inwardly sloping surface 760. Sloping surface 760 is positioned to interact with hump 756 as inner housing 754 is translated into outer housing 752 at the time when portal 722 is approximately medially disposed within shroud portal 706. Inward movement of inner housing 754 ultimately causes surface 760 to collide with hump 756, thereby placing an increasing pressure upon diaphragm 142" until hub 50' is frangibly separated from the diaphragm 142". Note that the slope of surface 760 determines the mechanical advantage and, therefore, the rate of change of force which must be imposed upon inner housing 754

relative to outer housing 752 to actuate a lancing cycle. The currently preferred material for lancets 700 and 750 are the same as the material specified for parts of strip 600.

Note that the force to actuate lancet 750 is transverse to the direction of travel of lancet tip 140'. Another embodiment of a one-step lancet, i.e., one-step lancet 800, is seen in Figures 24-26. There are two major differences between lancet 800 and lancet 750. The first difference is that lancet 750, like lancet 700, preferably comprises a frangible self-contained sterile seal disposed between a blade exit and reentry port (e.g. port 722) and an internal surface of a side of an outer housing (e.g. side 714). In this manner, no additional packaging is required to prevent contamination of a lancet blade before use. The second difference is the direction of actuation. As earlier stated, the actuation of lancet 750 is in a direction transverse to the motion of tip 140' during lancing, while the direction of applying a force for actuating lancet 800 is parallel to the direction of movement of lancet tip 140'.

Since the actuation of lancet 800 and the direction of travel of lancet tip 140' are disposed parallel one to the other; there is no opportunity for use of a frangible part out of the line of travel of lancet tip 140'. For this reason, prior to use, lancet 800 is preferably packaged inside a sealed package 802, an example of which is seen in Figure 24. Such packages are well known in the medical industry and are commonly used to protect lancets in transport and prior to use.

Referring to Figure 25, lancet 800 comprises an outer housing 804 and an inner housing 806. Inner housing 806 is made to slide within outer housing 804. Inner housing 806 comprises a plunger or push end 808 and an end 810. End 810

comprises a lancet tip 140' exit and reentry port 812 and a raised shroud 814. In combination, inner housing 806 and outer housing 804 comprise a lancet and lancet activation mechanism similar in form and function to that comprising hump 756 and sloped surface 760, except that the lancet activation mechanism is aligned to operate as outer housing 804 and inner housing 806 are moved relative to each other, with the outer housing 804 moving away from a lance site.

Outer housing 804 comprises a rim 816, which provides a housing 804 retarding part which permits outer housing 804 to be retracted from the lance site as plunger 808 is moved relative to outer housing toward the lance site to actuate lancet 800. The state of lancet 800 following a lancing procedure is seen in Figure 26.

A lancet 900 comprising an additional mechanical advantage that provides an additional force to frange a hub 50" is seen in Figures 27 and 28. Similar to lancets 750, 800 and 850, lancet 900 comprises an outer housing 902 and an inner housing 904 which act as inner housing 904 is moved relative to outer housing 902 to actuate the lancet. The source of the mechanical advantage is a pivot pin 906 medially and proximally disposed relative to a lancet blade 500', disposed within inner housing 902.

Outer housing 902 further comprises a curved surface and associated part 908 which is juxtaposed to a lance site during a lancing procedure. Part 908 comprises a lancet tip exit and reentry portal 910, which also acts as a shroud. Outer housing 902 also comprises an opening 912, which permits a portion 914 of inner housing 904 to be slidably translated during activation of lancet 900.

Inner housing 904 comprises a lancet compartment 40", which is similar to cavity 40'. Inside compartment 40", inner housing 904 comprises a hub 50", a spring

110 and a lancet blade 500'. Lancet blade 500' comprises a medially disposed blade stem 915 and a blade tip 140". Exterior to compartment 40", inner housing 904 comprises an aperture disposed about pivot pin 916, which provides a fulcrum and, in combination with the effective lever arm provided by portion 914, increases the mechanical advantage as portion 914 is translated inside outer housing 902 through opening 912. Inner housing 904 further comprises blade guides 918, 920, 922 and 924. Note that guide 924 is separated into two parts, making way for an anchor slot 62 for lower spring end 122. Inner housing 904 also comprises a curved surface 926, which is an arc of a circle drawn with pivot pin 906 at the center. Note that the curvature of outer housing part 908 conforms with the curvature of surface 926.

Curved surface 926 comprises an exit and reentry port 928 for lancet tip 140".

Before activating lancet 900 by translating portion 914 into outer housing 902, an outer periphery 930 is preferably sealed against an inner surface portion of part 908 to permit lancet 900 to be transported and stored without additional packaging. In a manner similar to the frange mechanism provided by hump 756 and surface 760, outer housing 902 and inner housing 904 act in concert to frange hub 50" free and to activate lancet 900 as inside housing 904 rotates about pivot pin 906 to bring port 928 in alignment with portal 910 and to cause lancet tip 140" to traverse outward to the lance site and then return to a secure rest state as seen in Figure 28.

Blade 500' differs from blade 500 in two significant ways. First tip 140" comprises a wider, but shallower cutting edge. Such a blade is useful in longer but more superficial cuts, such as cuts on an infant. Second stem 915 is medially

disposed upon blade 500'. The medial position is particularly important in a device which rotates about a pivot pin as lancet 900 does.

It is currently preferred that materials used for lancets 700, 750, 800, and 900 are the same as those listed for lancet strip 600.

5 The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency
10 of the claims are therefore intended to be embraced therein.

What is claimed is:

CLAIMS

1. A one-time-use, disposable lancet actuating apparatus which is triggered to discharge a lancet tip from a lancet housing and to retract the lancet tip into the lancet housing for safe disposal, said apparatus comprising:
 - 5 the lancet housing comprising at least one frangible part;
 - a lancet blade disposed within the lancet housing and comprising the lancet tip;
 - means for storing energy which is also disposed within the lancet housing and which is selectively released from a state of high potential energy to provide a unidirectional angular form of kinetic energy, said energy storing means comprising means for driving said blade linearly outward from and inward into said lancet housing as a result of said angular form of kinetic energy and for communicating with a catch which further communicates with a triggerable release;
 - 10 said lancet housing further comprising a hub which in an initial state is an integral but frangibly releasable part of said lancet housing, said hub comprising the catch and a base which communicates through a frangibly releasing part to the rest of said lancet housing as a part of said triggerable release and which communicates through the hub to the catch for said communicating means; and
 - 15 said frangibly releasing part comprising a pair of concentric grooves, at least one of said grooves circumscribing said base, said grooves in combination comprising a region, interposed between said grooves, in which substantially all segments of said

lancet housing which frange when the base of the hub is placed under stress and separated from the rest of the lancet housing are disposed.

2. A one-time-use, disposable lancet actuating apparatus according to

5 Claim 1, wherein said lancet housing comprises an orifice through which the lancet tips travels outwardly and inwardly.

3. A one-time-use, disposable lancet actuating apparatus according to

10 Claim 2, wherein said lancet housing further comprises a shroud disposed about said orifice, said shroud comprising a raised surface which acts to contain flow of fluid resulting from action of the lancet.

4. A one-time-use, disposable lancet actuating apparatus according to

15 Claim 1, wherein said lancet housing comprises a linear strip comprising a plurality of frangibly connected lancet devices.

5. A one-time-use, disposable lancet actuating apparatus according to

Claim 1, wherein said lancet housing comprises only a single lancet device.

20 6. A one-time-use, disposable lancet actuating apparatus according to

Claim 1, wherein said apparatus comprises two housing parts, said lancet housing and a second housing, said lancet housing disposed as an inner housing slidably disposed inside said second housing, said lancet and second housings being moved one relative

to the other to form said triggerable release for frangibly separating the hub from the lancet housing.

7. A one-time-use, disposable lancet actuating apparatus according to

5 Claim 6, wherein said lancet and second housings, in combination, comprise means for moving said lancet housing relative to said second housing in a direction which is transverse to direction of linear movement of said lancet tip.

8. A one-time-use, disposable lancet actuating apparatus according to

10 Claim 6, wherein said lancet and second housings, in combination, comprise means for moving said lancet housing relative to said second housing in a line of movement substantially parallel to direction of linear movement of said lancet tip.

9. A blade for a self-powered lancet comprising:

15 a sharpened lancet tip;
an arched slot for use in cam/cam follower relation with a kinetic energy source for translating rotary motion of the kinetic energy source to linear motion of the lancet tip; and

means for releasably affixing said blade to a blade holder whereby the blade is disposed for automatic dispensing and assembly into the lancet.

20 10. A blade according to Claim 9, further comprising edges formed by laser cutting technology.

11. A blade according to Claim 9, further comprising edges formed by coining.

12. A method for operating a one-time-use, disposable lancet comprising an outer housing, an inner housing comprising a self-powered lancet apparatus and an exit orifice from which a lancet blade tip is driven outwardly to lance and then retracted inwardly for safe storage thereafter, and a frangible sealed connection between the outer housing and inner housing, for the purpose of maintaining sterility of the lancet blade tip, comprising the steps of:

10 placing the exit orifice against a surface to be lanced;
moving the outer housing relative to the inner housing to frangibly break the sealed connection; and
triggering the self-powered lancet apparatus to cause the lancet tip to be driven outwardly through the orifice and then inwardly through the orifice.

15 13. A method according to Claim 12, wherein the moving step and triggering step comprise a single continuous motion.

14. A method according to Claim 12, wherein the triggering step comprises a motion transverse to the motion of the moving step.

15. A method according to Claim 12, wherein the moving and triggering steps, in combination, comprise moving at least one surface across at least one opposing inclined plane.

5 16. A method for using a one-time-use, self-powered, disposable lancet initially disposed as a single lancet in a lancet strip, said strip comprising a plurality of lancets with a blank section interposed between each lancet, comprising the steps of:

- 10 (a) frangibly separating a first blank section thereby breaking a sterile barrier and exposing a hygienic lancet blade tip exit and reentrance orifice, through which the blade travels to lance, and a shroud which surrounds said orifice;
- (b) disposing the shroud and associated orifice against a site to be lanced;
- (c) lancing the site;
- (d) frangibly separating the lancet used to lance the site from the strip; and
- (e) discarding the lancet into a proper medical waste container.

15

17. A method according to Claim 16, comprising repeating steps (a) through (e) to lance a subsequently chosen site.

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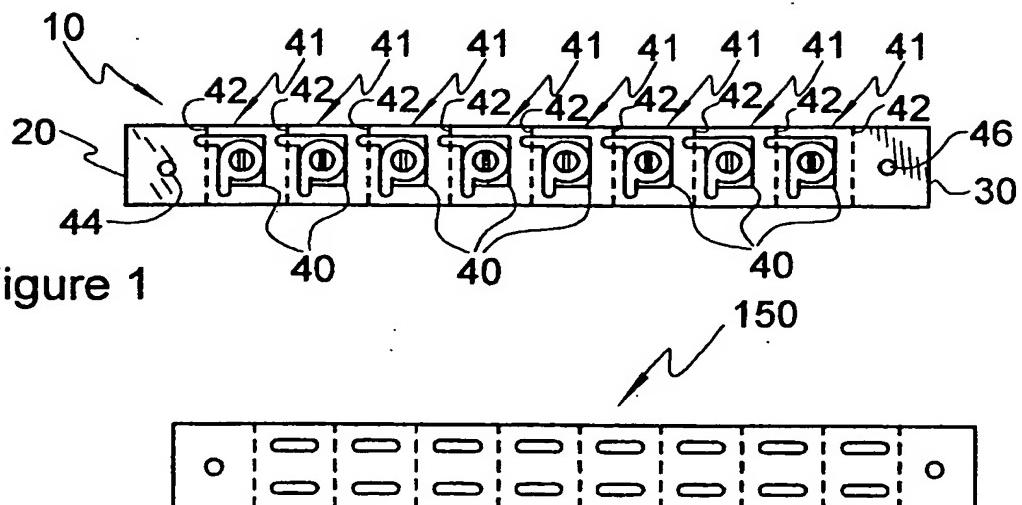
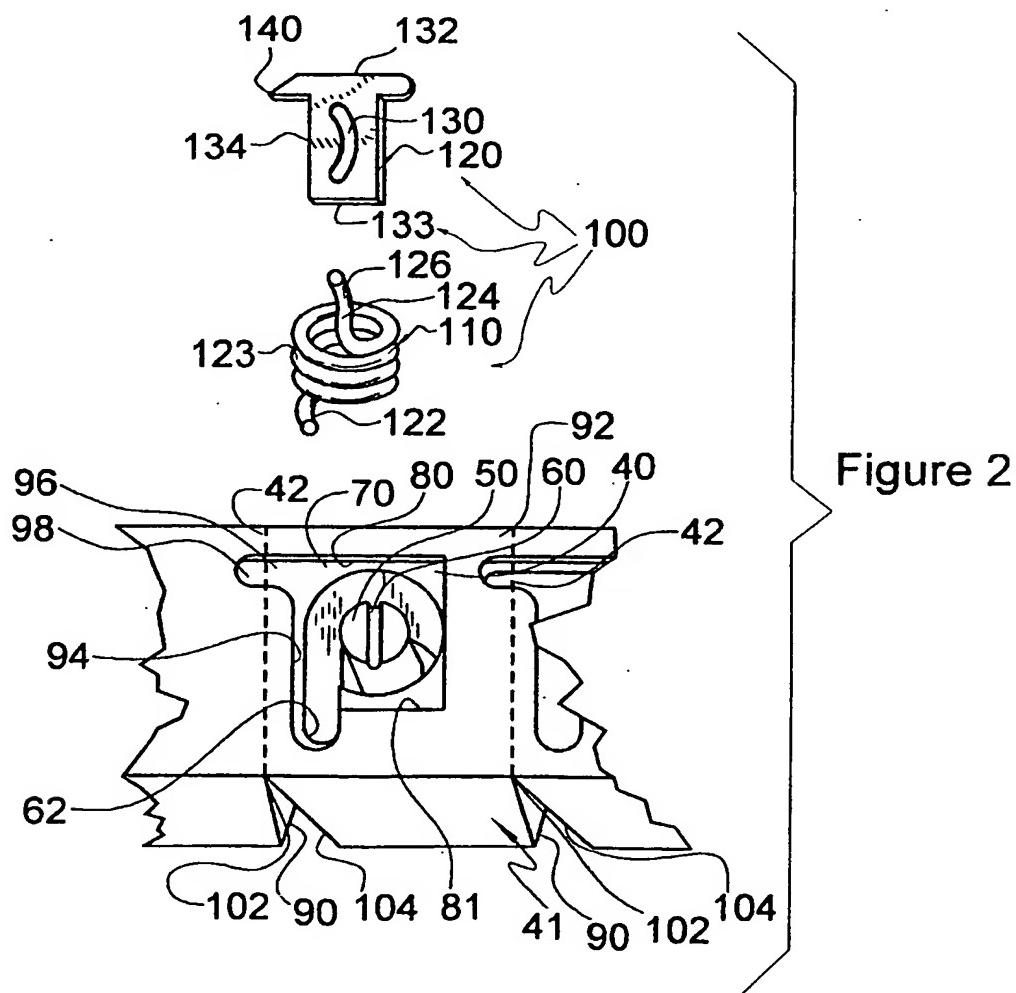


Figure 3



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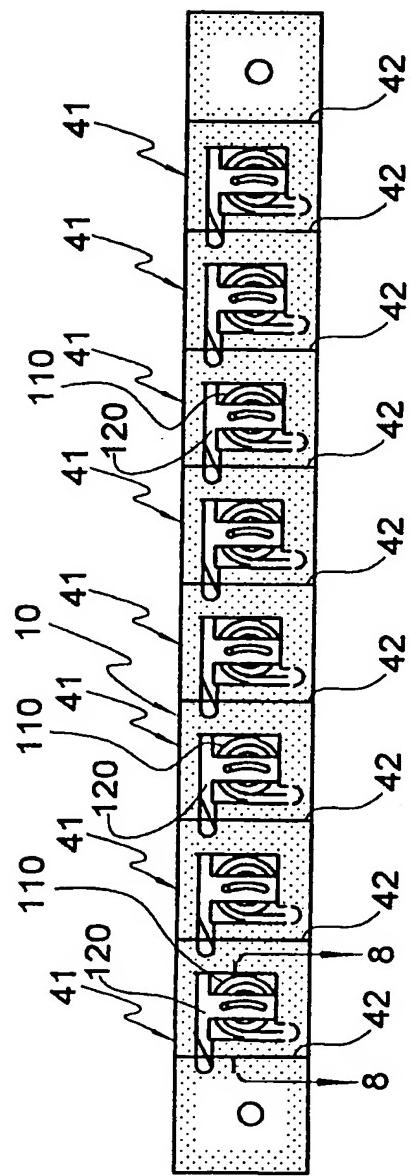


Figure 4

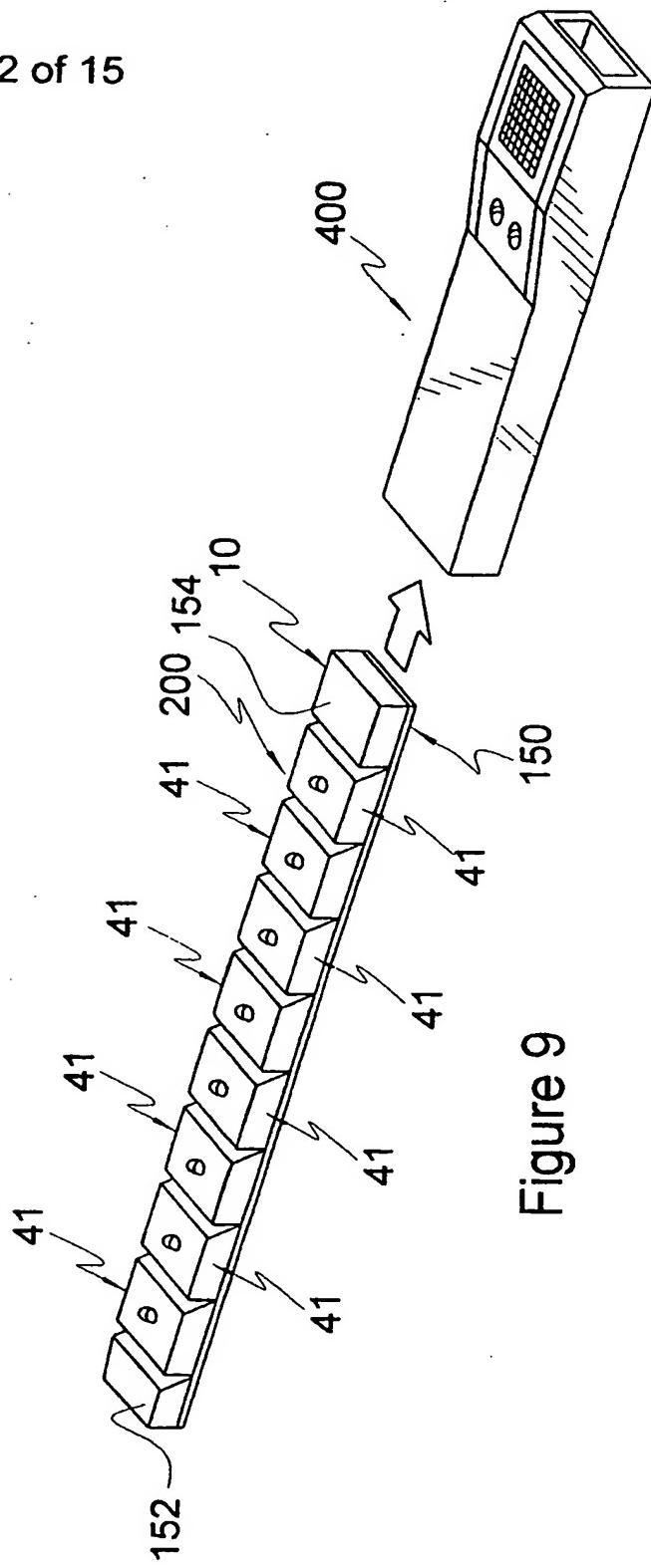


Figure 9

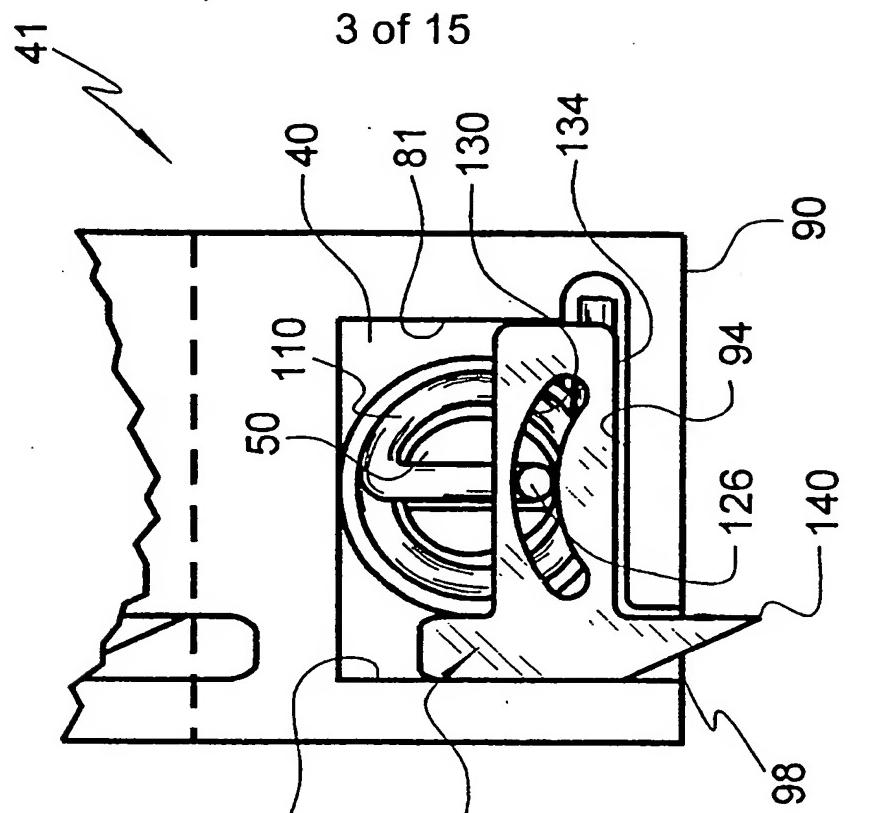


Figure 6

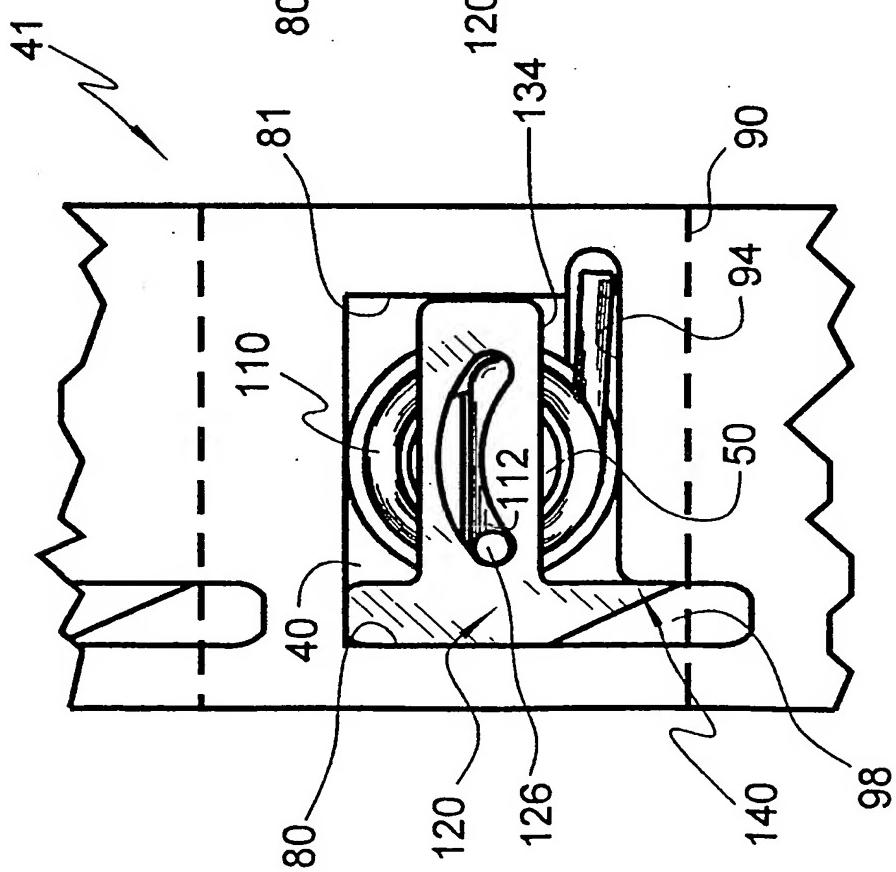
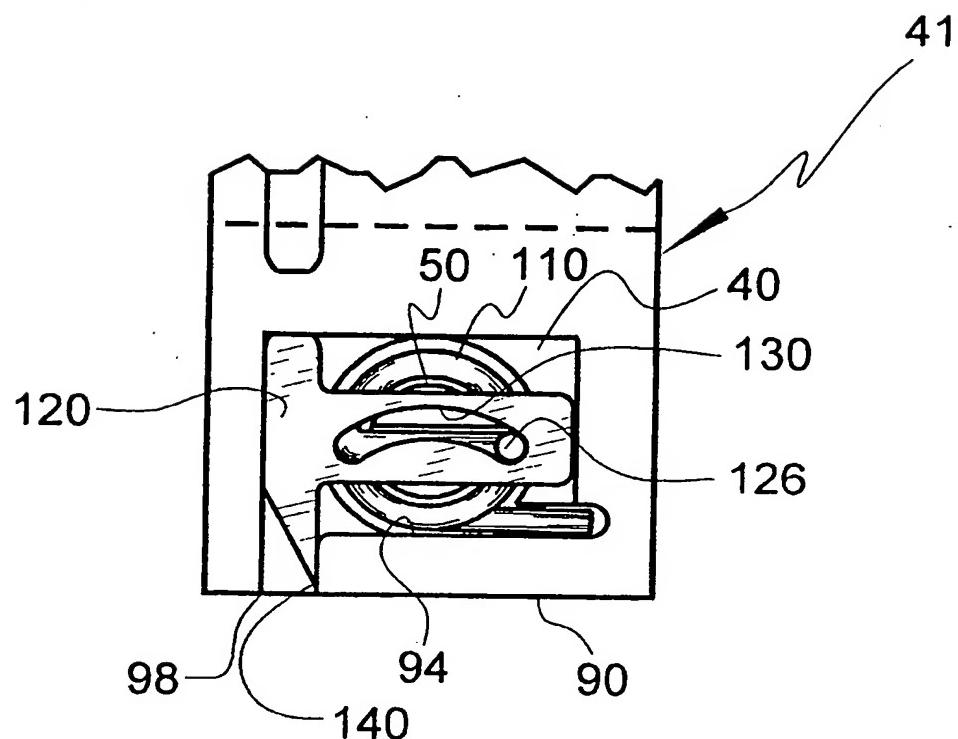
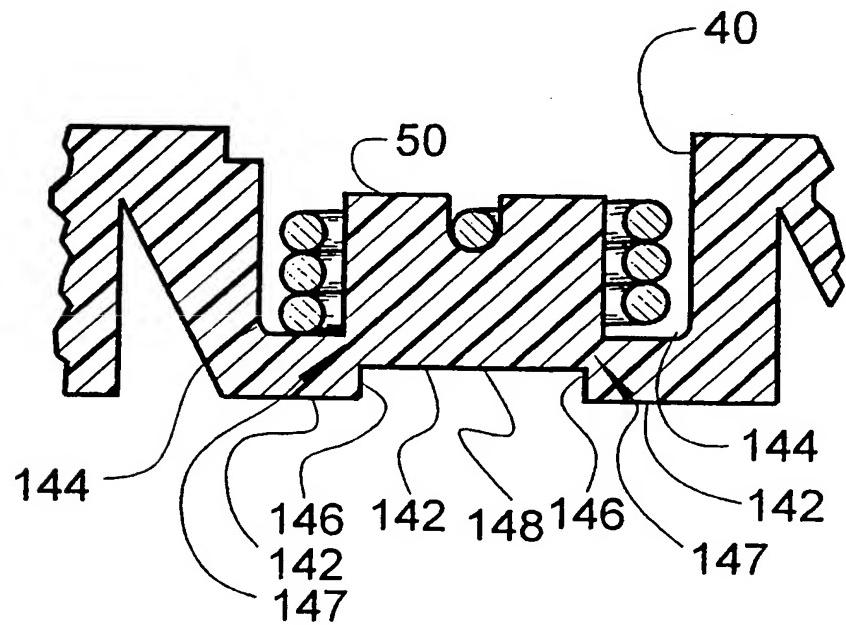
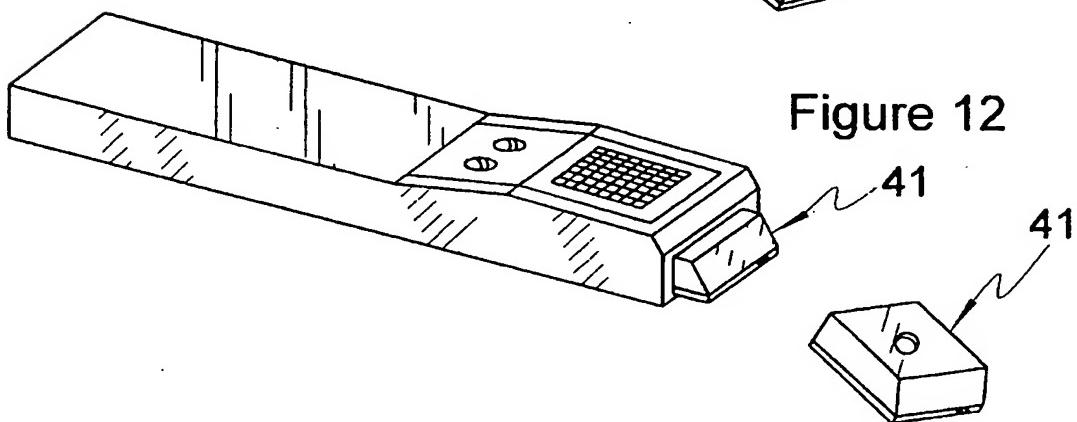
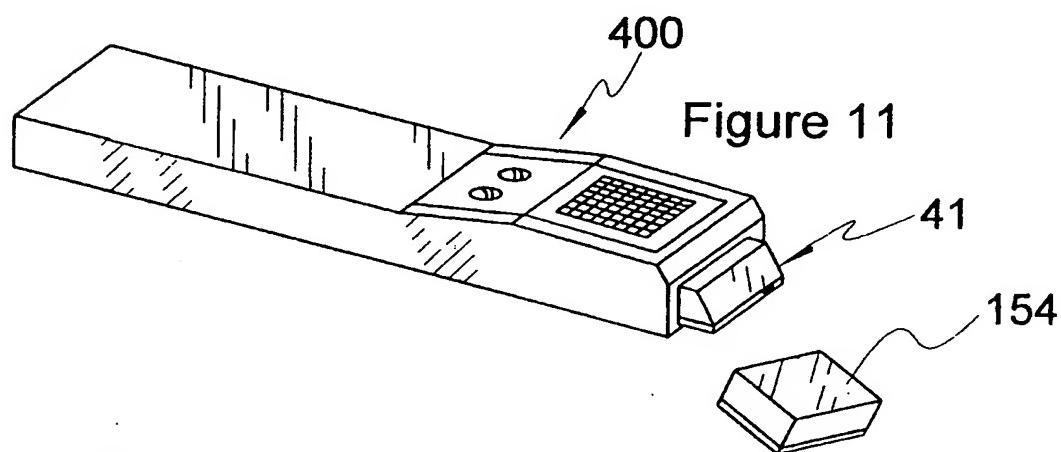
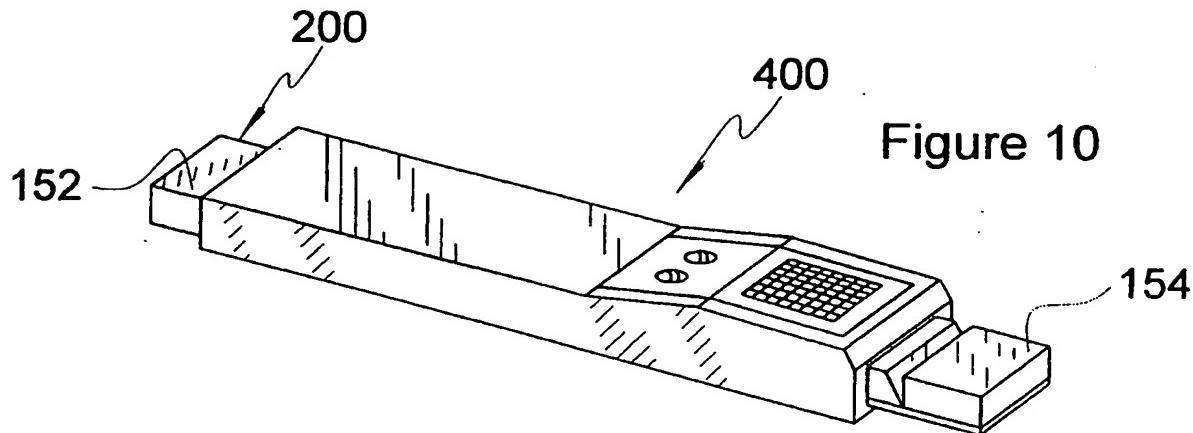


Figure 5

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Figure 7**Figure 8**

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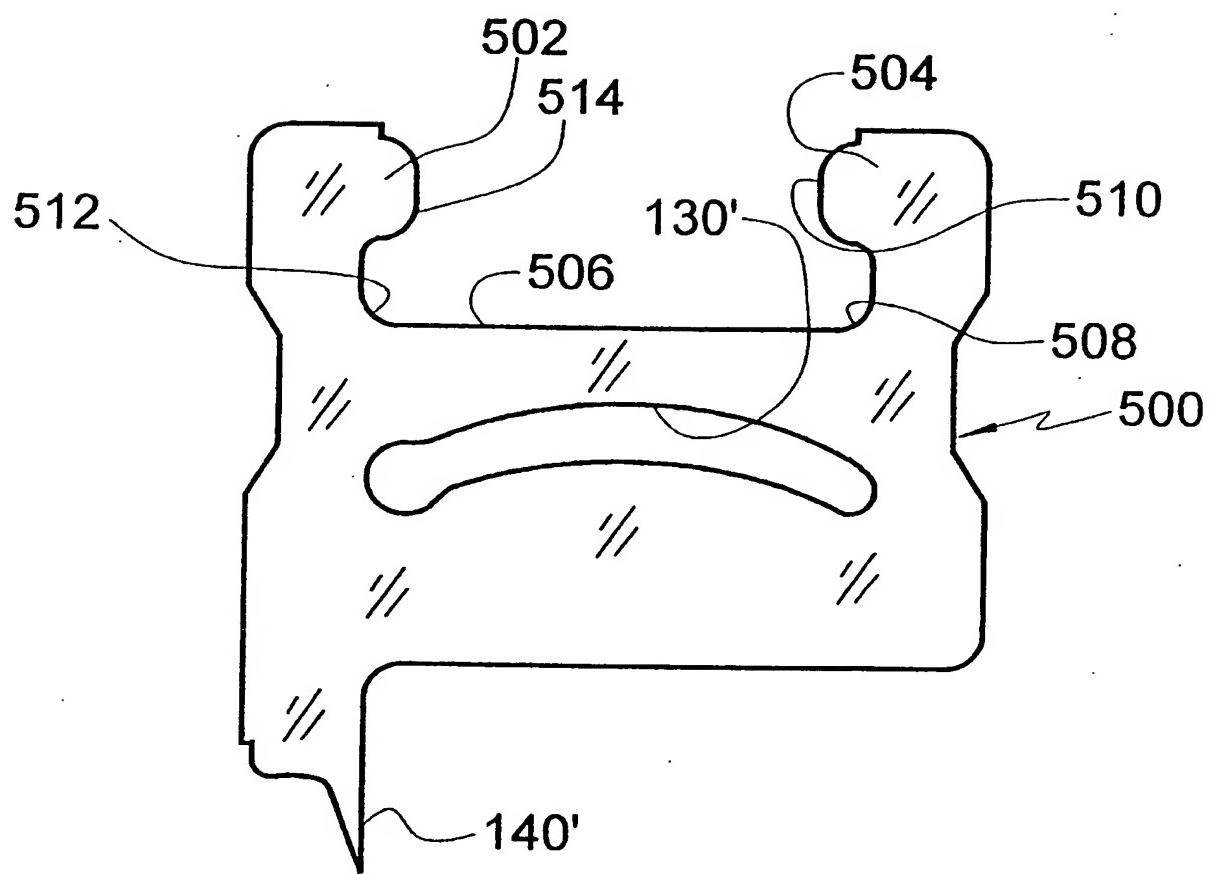


Figure 13

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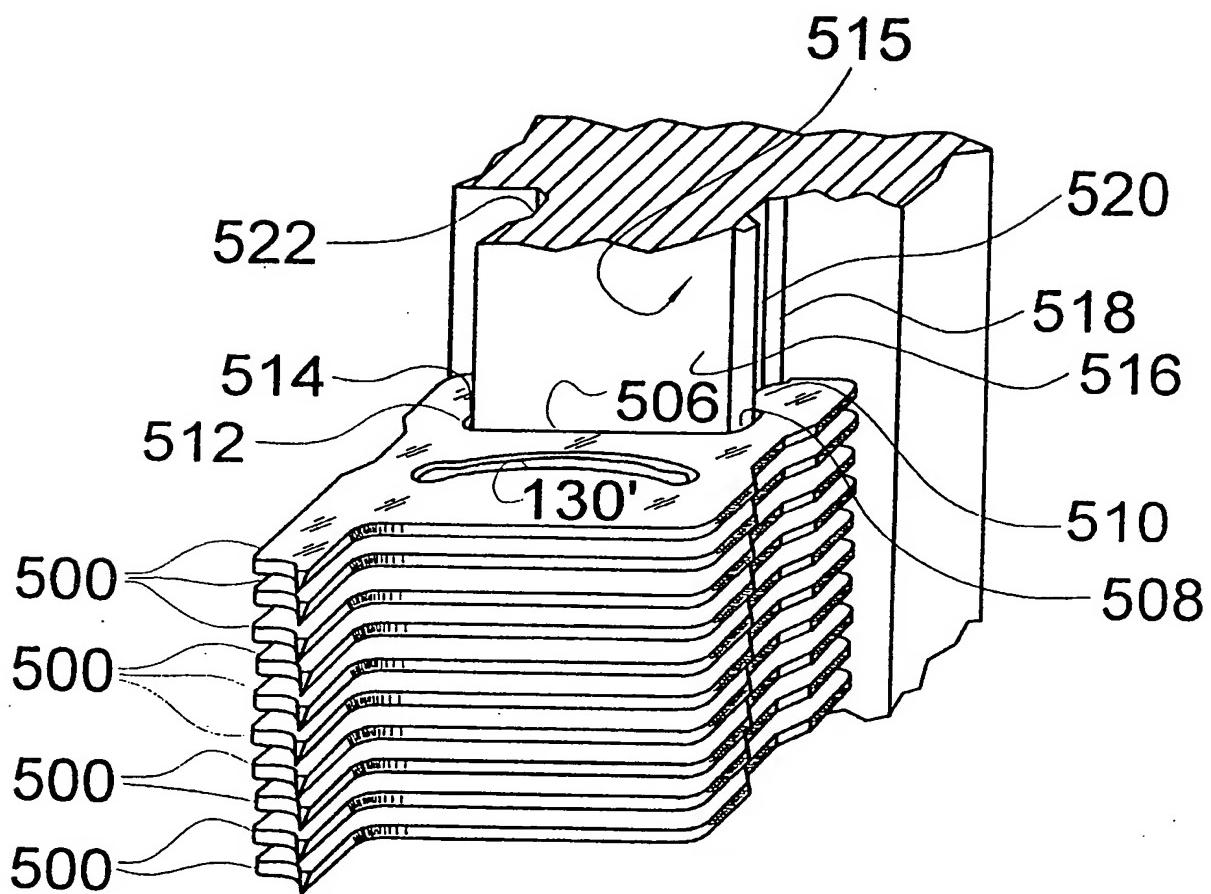


Figure 14

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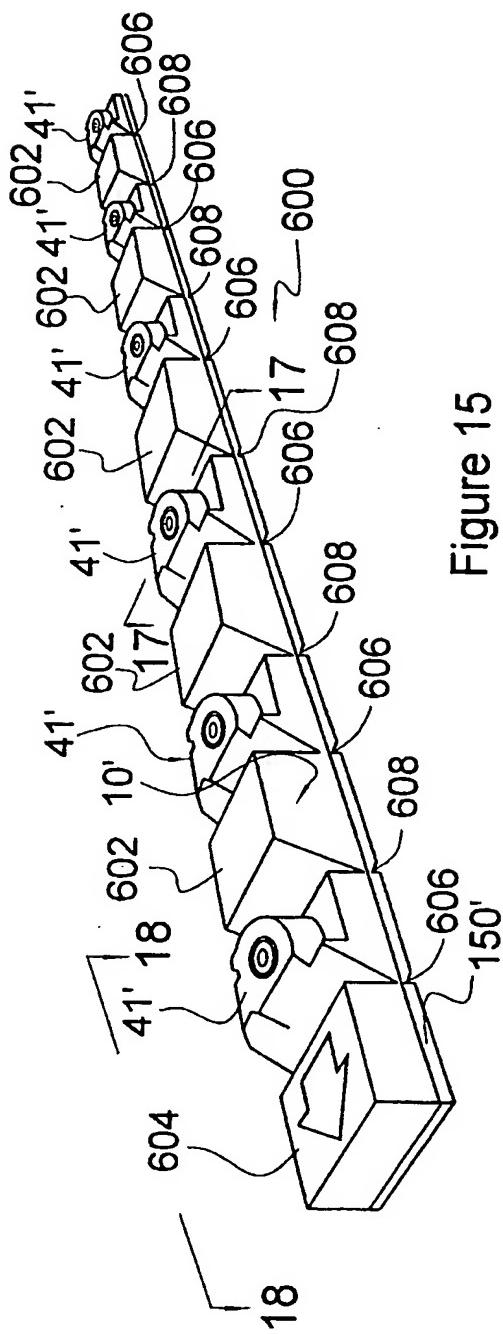


Figure 15

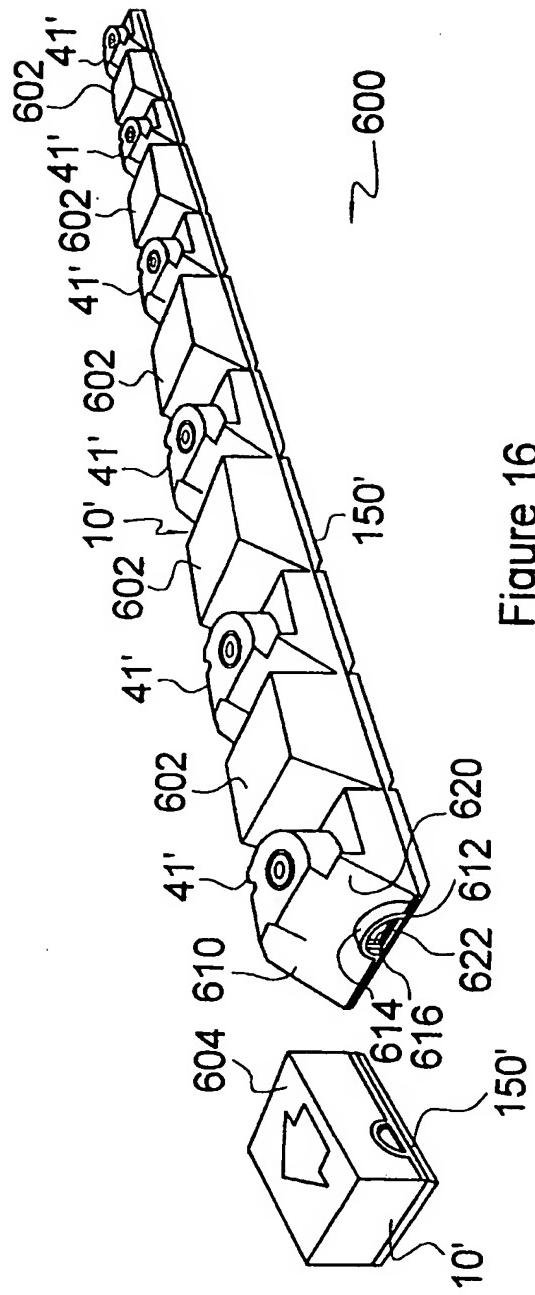


Figure 16

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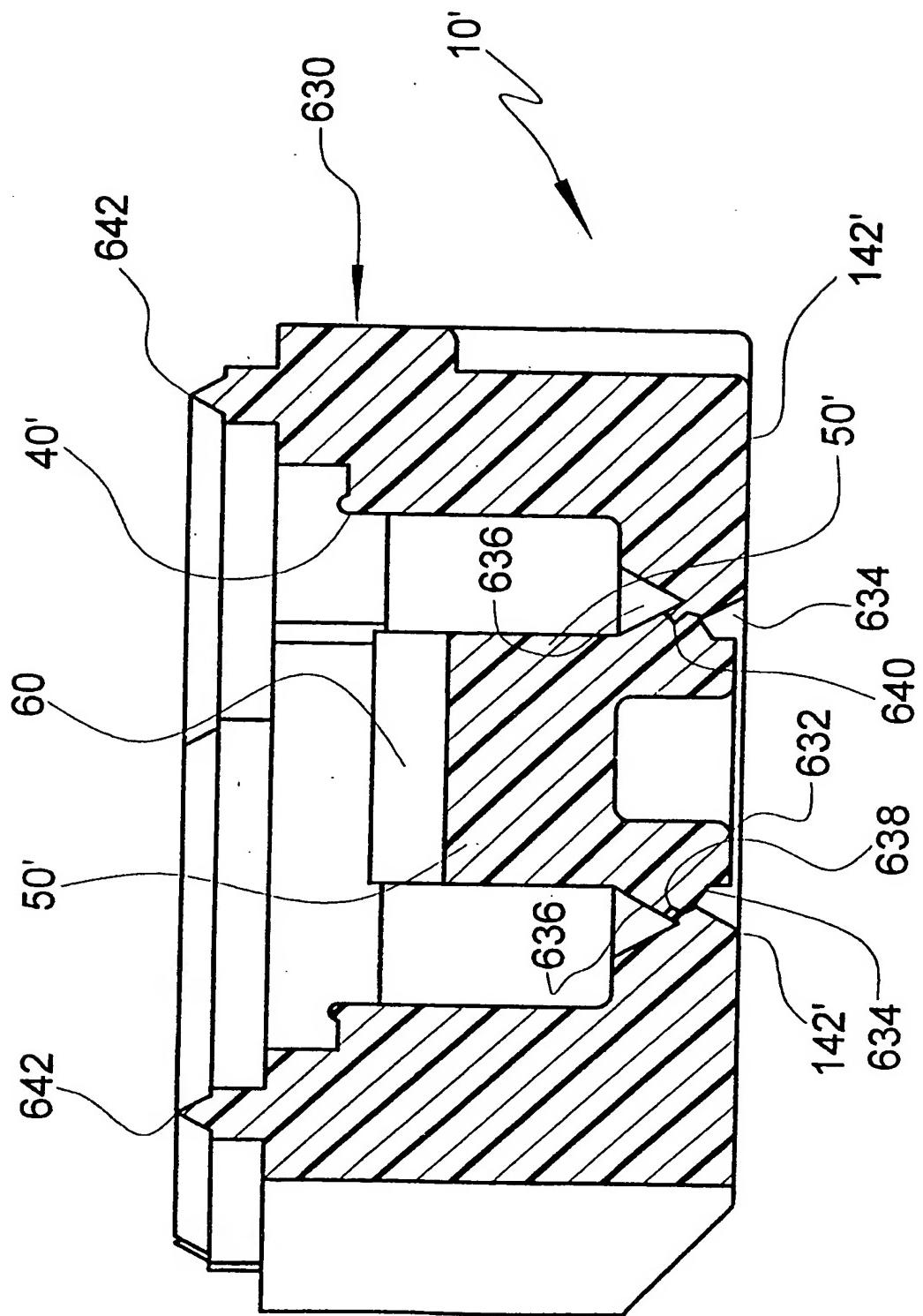


Figure 17

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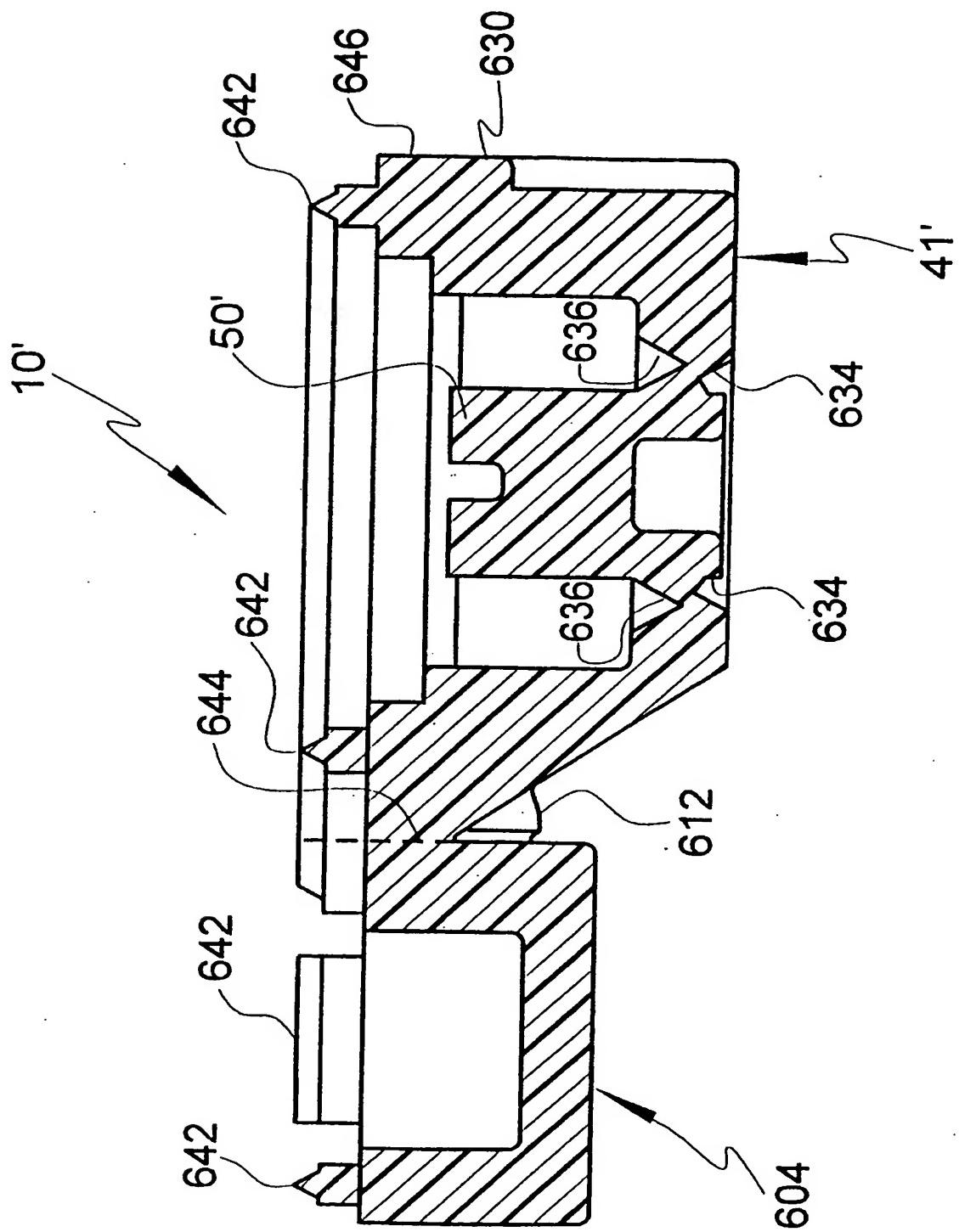


Figure 18

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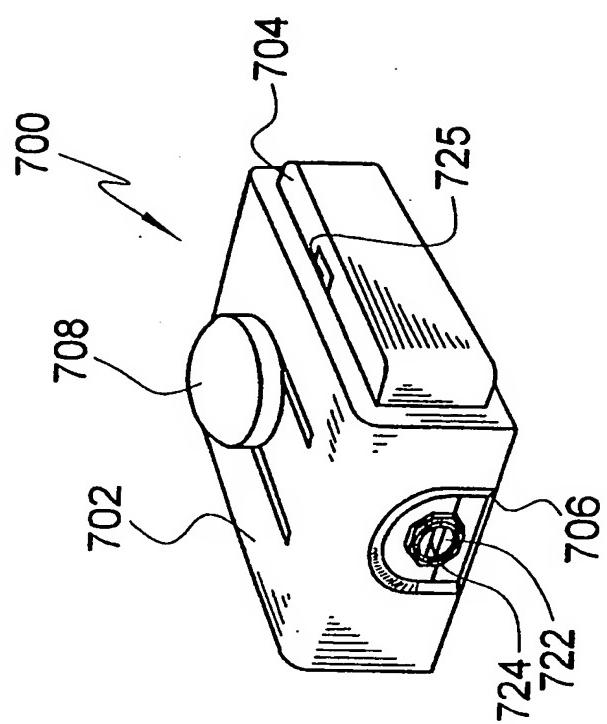


Figure 20

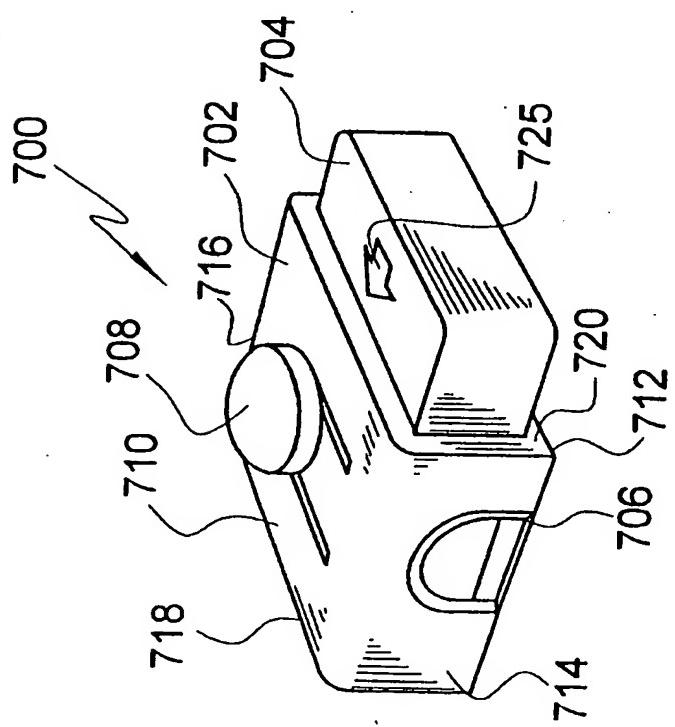


Figure 19

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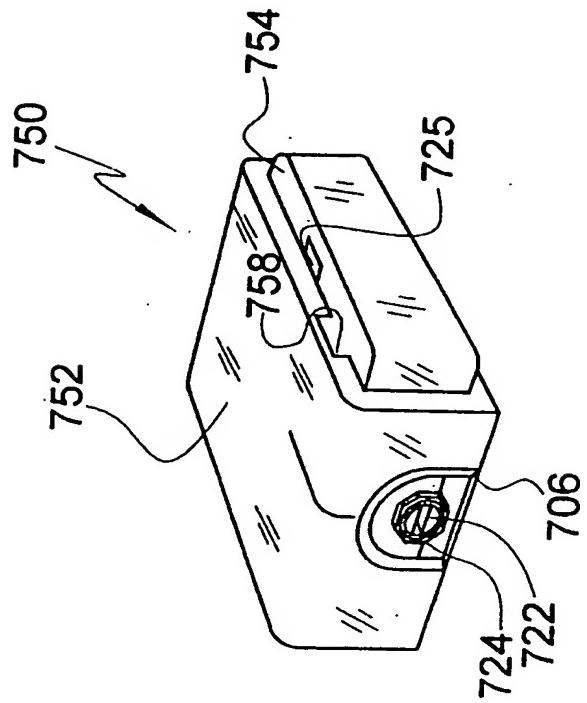


Figure 22

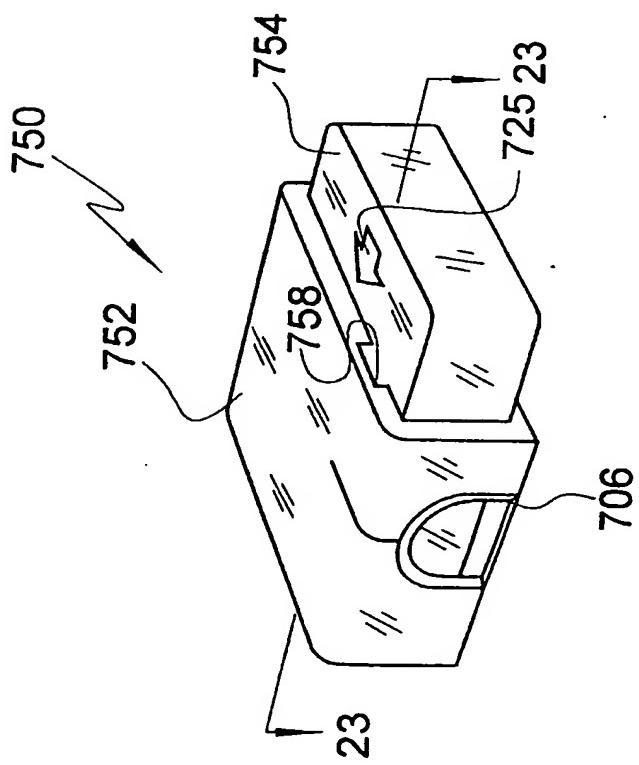
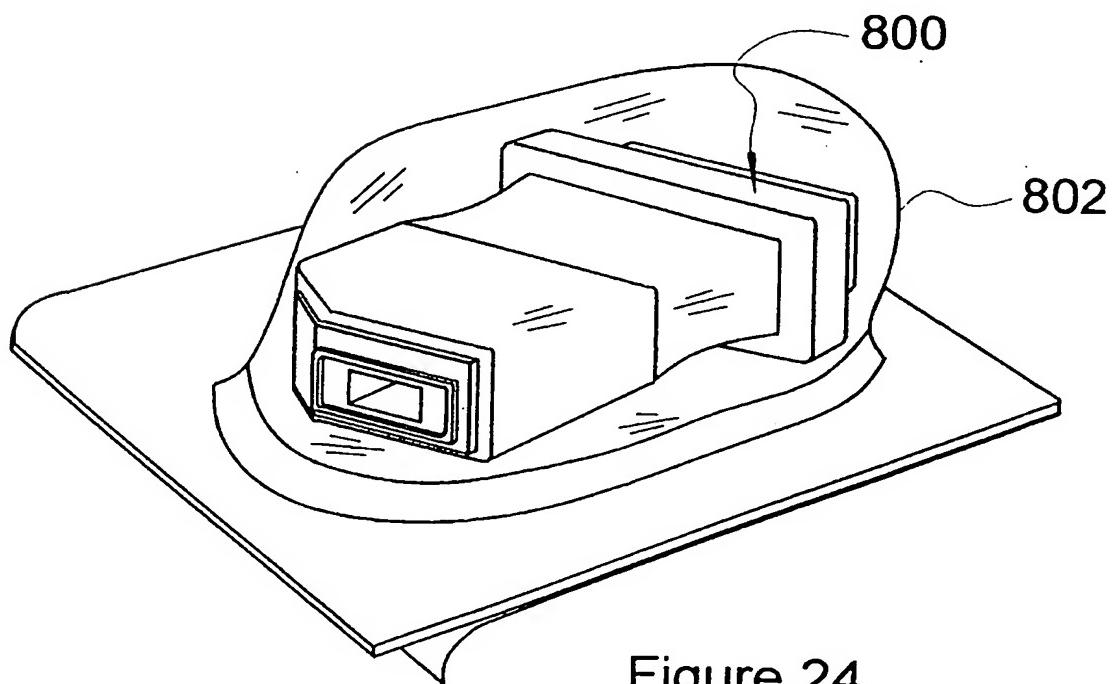
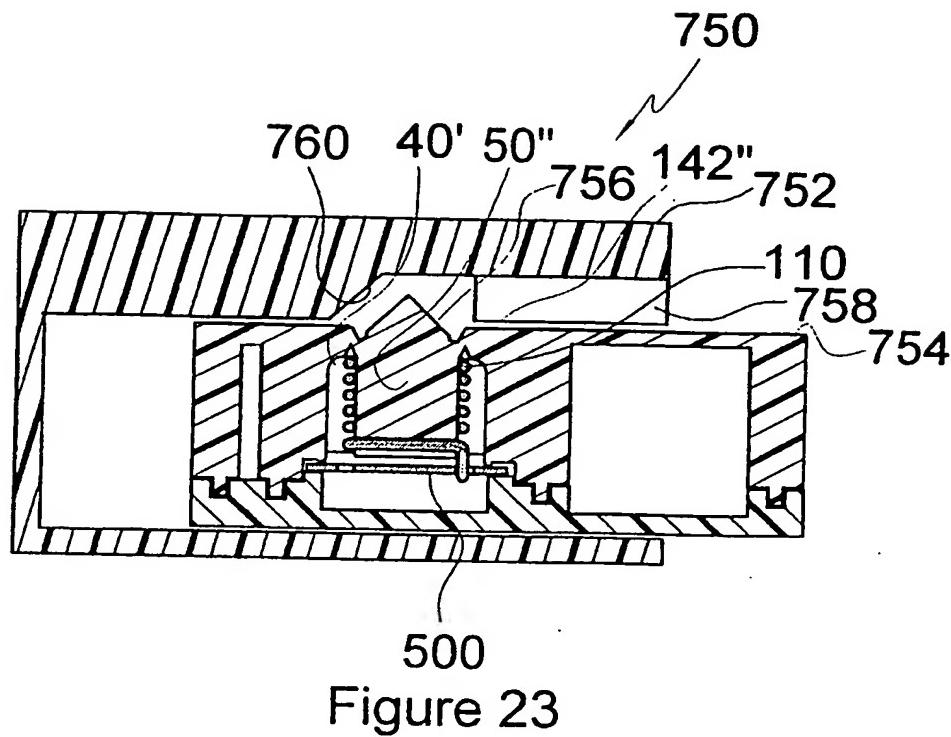


Figure 21

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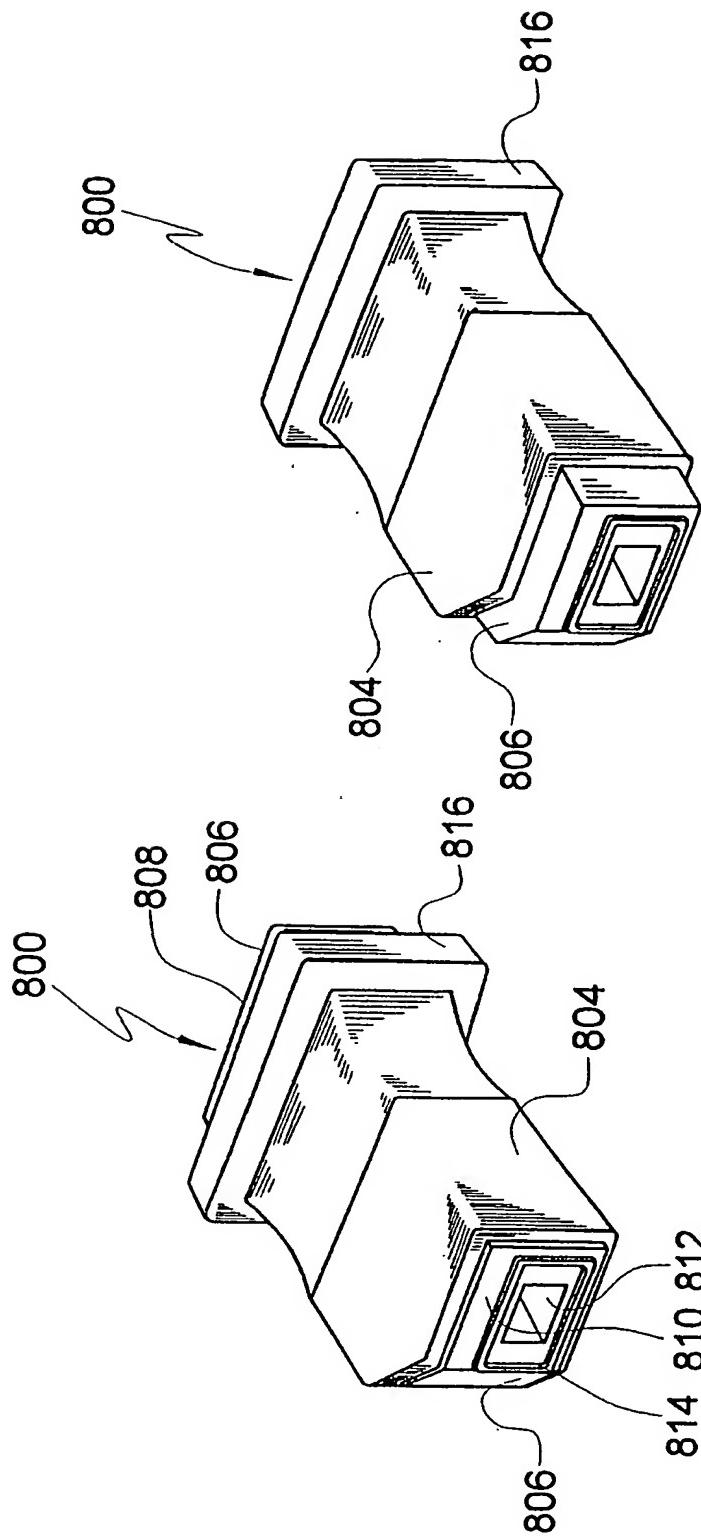


Figure 25

Figure 26

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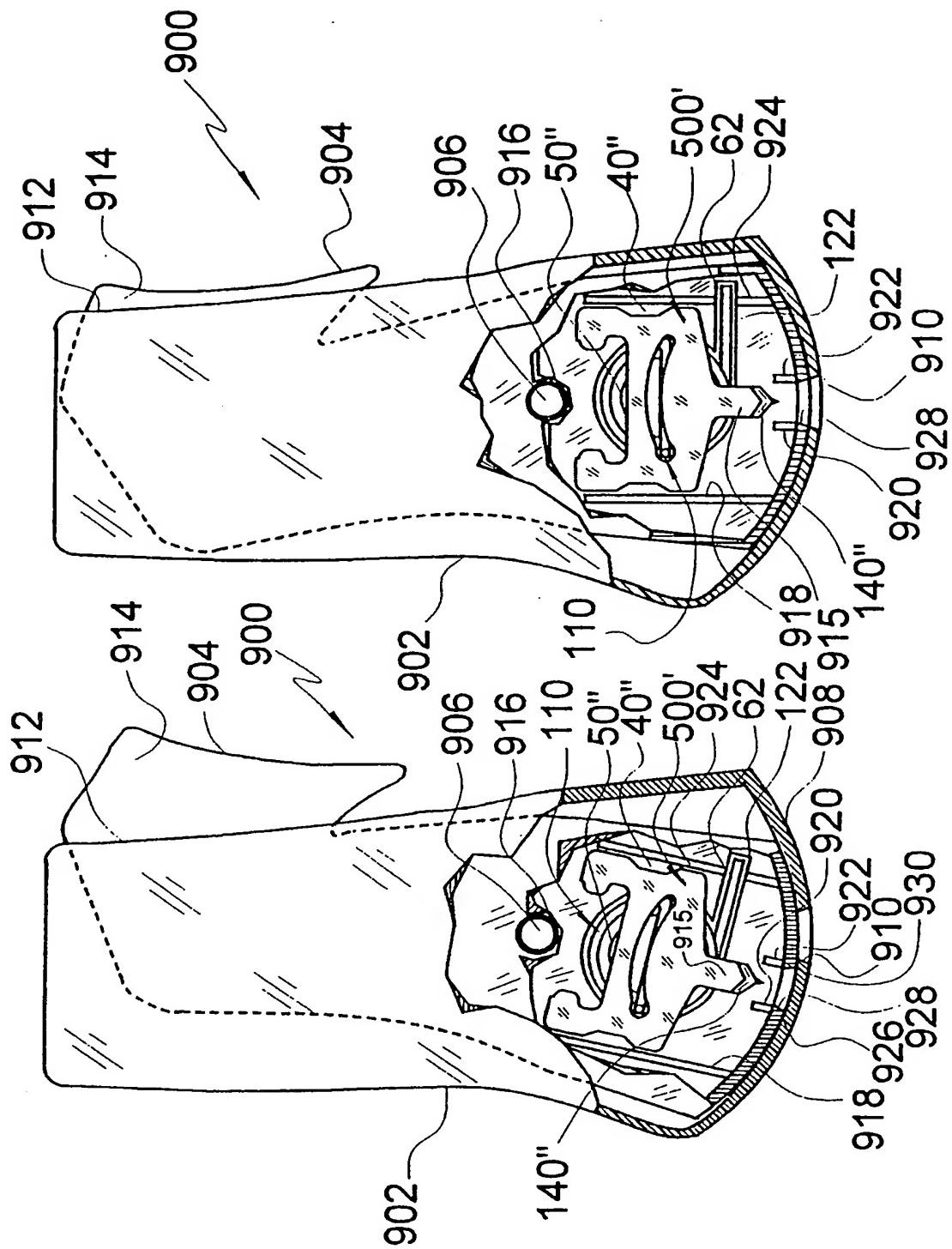


Figure 28

Figure 27

INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/17426

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/32

US CL :606/182

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 204/206; 606/181, 182

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,X	US, 5,514,152 A (SMITH) 07 May 1996, whole document.	1-8, 12, 14-17
Y	US, 4735,203 A (RYDER et al) 05 April 1988, whole document.	9-11
Y, P	US, 5,571,132 A (MAWHIRT et al.) 05 November 1996, whole document.	9-11
Y	US, 5,395,388 A (SCHRAGA) 07 March 1995, whole document.	9-11

Further documents are listed in the continuation of Box C. See patent family annex.

Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 13 FEBRUARY 1998	Date of mailing of the international search report 02 MAR 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer NANCY MULCAHY Telephone No. (703) 308-0729
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